

Atty Dkt. No.: 10010186-1  
USSN: 09/848,869

### REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow claims 7, 9-14, 16, 18-20 and 22-24; the only claims pending and currently under examination in this application.

#### Formal Matters

Claims 7, 9-14, 16, 18-20, and 22-24 are pending.

Claims 7, 9-14, 16, 18-20, and 22-24 were examined and rejected.

Claims 7, 16, 20 and 22-24 are amended. Support for the amendments can be found throughout the specification and claims as originally filed. Specifically, support is found at page 4, final ¶, and page 5, ¶ 2. These amendments are made solely for the purpose of expediting prosecution and advancing the case to issuance. No new matter has been added.

Applicants respectfully request reconsideration of the pending claims in view of these amendments and the remarks made below.

#### Specification

The specification is objected to because certain documents have allegedly been improperly incorporated by reference. Specifically, the Office asserts that the incorporation by reference set forth on page 14, last paragraph, is improper because it does not identify with any detail the subject matter that is incorporated.

The Office cites *Advanced Display Systems, Inc. v. Kent State University* (Fed. Cir. 2000) to support its position. However, the Applicants contend that the cited case stands for the proposition that "the standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity." See *Advanced Display Systems, Inc.*, 54 USPQ2d at 1679.

Accordingly, the Applicants respectfully submit that one reasonably skilled in the art would clearly understand Applicants' incorporation language to be effective for incorporating all of the documents cited within the specification by reference. The Applicants contend that such a global "incorporation by reference" is standard industry practice, as evidenced by the numerous patents that have issued with analogous incorporation language.

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For instance, a search of the PTO website pertaining to similar phraseology as used by the Applicants identifies thousands of issued patents all using similar language. This high number of issued patents using the similar phraseology as that used by Applicants is not only indicative of the practice in the industry but also the usual PTO practice to allow applications using that language.

Applicants would, specifically, like to draw the Examiner's attention to two issued U.S. patents where almost the exact same phraseology is used to incorporate a multiplicity of cited references. US Patent No. 6,346,553 uses the phrase: "The above-referenced patents and publications are hereby incorporated by reference in their entirety." See the last sentence of Example 9. Additionally, US Patent No. 5,686,513 uses the phrase: "All patents and other publications are hereby incorporated by reference in their entirety." See Summary of Invention, last sentence before the Detailed Description. The Applicants see no material difference between these incorporation statements and the statement used by the Applicants on page 14, last sentence, wherein the application sets forth: "All patents and publications mentioned herein, both *supra* and *infra*, are hereby incorporated by reference."

The Applicants would, therefore, like to invite the Office to explain why the phraseology as used in the thousands of other issued patents, and the '533 and '513 patents specifically, constitute appropriate incorporations by reference and the Applicants' analogous statement of incorporation does not. In view of the foregoing discussion, the Applicants respectfully submit that the incorporations by reference in question meet the requirements of MPEP § 608.01(p) and respectfully request that this objection be withdrawn.

**Rejection under 35 U.S.C. § 102**

Claims 7, 9-14, 16, 18-20, and 22-24 are rejected under 35 U.S.C. § 102(b) as being either anticipated by, or in the alternative rendered obvious over, Meade (USPN 5,952,172). Specifically, the Office asserts that Meade discloses a hybridization method that anticipates or renders obvious the claimed method. The Applicants respectfully traverse the rejection.

According to the MPEP, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art

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reference. Additionally, the identical invention must be shown in as complete detail as is contained in the claim. See MPEP 2131.

The present invention is directed to methods for detecting the binding of a probe with a target molecule. The basis of the invention as amended is that free metal ions can be used to "dope" a transition metal ligand-labeled probe that has previously bound to a target nucleic acid to form a complex that is conductive and capable of producing a detectable signal. Each of the rejected claims explicitly recites a free metal ion as a distinct element.

Meade's disclosure, on the other hand, is directed to methods of labeling nucleic acids with electron transfer agents to form transition metal ligand complexes. Meade discusses using these transition metal ligand complexes to generate a light signal. Metal ions that are complexed in a transition metal ion complex are not free metal ions and cannot be inserted between base pairs of a nucleic acid duplex. Accordingly, Meade fails to disclose, teach or fairly suggest any method or composition that employs free metal ions.

The Office points to Meade col. 7, third paragraph, to provide a teaching of metal ions. However, this section actually teaches transition metal ligand complexes, not free metal ions. The Office points out that at Meade col. 11, first full paragraph, is set forth "all combinations of electron donors and acceptors." However, none of the combinations listed refer to free metal ions. In fact, in all the embodiments set forth in Mead the electron donor and/or acceptor are attached to a nucleic acid. See for example Column 21, second full paragraph. At no point does Mead describe any method that employs free metal ions. The concept of adding free metal ions to a probe/target duplex labeled with a transition metal ligand complex to produce a conductive complex is neither addressed nor suggested in the disclosure of Meade.

Accordingly, because Meade fails to disclose, teach or fairly suggest free metal ions, an element of the amended claims, it cannot be used to anticipate nor render obvious the currently pending claims. The Applicants, therefore, respectfully request this rejection be withdrawn.

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**Double Patenting**

The Office Action has provisionally rejected Claims 7, 9-14, 16, 18-20, and 22-24 under the judicially created doctrine of obviousness type double patenting over Claims 7-20 of co-pending Application No. 10/892,928 and Claims 22-41 of co-pending Application No. 10/798,982. In view of the enclosed Terminal Disclaimers over these two cited applications, these provisional rejections may be withdrawn.

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### CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order no. 1001086-1.

Respectfully submitted,

Date: June 22, 2005

By: 

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encs:

- Terminal Disclaimer over Application No. 10/892,928
- Terminal Disclaimer over Application No. 10/798,982

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